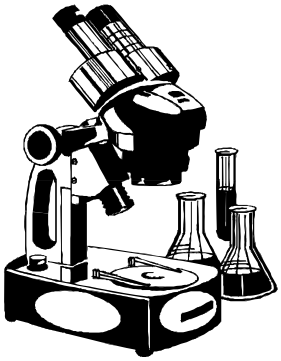

CLIA BITS

North Dakota Department of Health
Division of Health Facilities

Summer 2001

HCFA-Approved Certification Boards for Clinical Consultants and Directors of High Complexity Testing

The qualifications for the director and the clinical consultant of a laboratory that performs high complexity testing state that an individual who has earned a doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and is board certified is qualified. The approved certification boards for clinical consultants and directors of high complexity testing are as follows:

- American Board of Medical Microbiology (ABMM)
- American Board of Clinical Chemistry (ABCC)
- American Board of Medical Laboratory Immunology (ABMLI)
- American Board of Bioanalysis (ABB)
- American Board of Medical Genetics (ABMG)
- American Board of Histocompatibility and Immunogenetics (ABHI)
- American Board of Forensic Toxicology (ABFT)
- National Registry of Certified Chemists (NRCC)

An acceptable doctoral degree is a Ph.D., D.Sc. or M.D. If acceptable to the certification board, a D.D.S., D.V.M. or D.P.H. may fulfill the doctoral requirement.

Dermatophyte Test Media Quality Control

On Feb. 12, 2001, the Health Care Financing Administration Division of Laboratories and Acute Care Services issued a clarification of the quality control requirements for dermatophyte test medium (DTM). The CLIA guidelines use the standards found in the NCCLS "Quality Assurance for Commercially Prepared Microbiological Culture Media" document to determine the quality control applicable to laboratories using commercially prepared culture media. DTM contains cycloheximide and usually is supplemented with gentamicin and chlortetracycline. DTM is not specifically listed in the NCCLS document and is not included under the medium type listed as selective mycology media. Under CLIA, a laboratory that uses DTM must perform end-user quality control by performing media checks for sterility, selectivity and/or inhibition, the ability to support growth and the appropriate biochemical response for each batch or shipment of media.

Visit the new North Dakota Department of Health CLIA program website at www.health.state.nd.us/ndhd/resource/facilities/clia/.

Differences Between Calibration and Calibration Verification

Currently the calibration and calibration verification standards required by section 493.1217 apply only to high complexity, modified moderate complexity, in-house and unclassified testing. Laboratories that perform unmodified moderate complexity tests need to perform calibration procedures at least once every six months.

Calibration is the process of testing and adjusting an instrument, kit or test system to provide a known relationship between the measurement response and the value of the substance that is being measured by the test procedure. It involves running standard materials and readjusting the instrument to ensure that the values fall within certain specified ranges.

Calibration verification is the assaying of calibration materials in the same manner as patient samples to confirm that the calibration of the instrument, kit or test system has remained stable throughout the laboratory's reportable range for patient test results. This means running alternate material as a specimen at the same time and verifying that the test result falls within the established ranges. If reagents are obtained from a manufacturer and all of the reagents for a test are packaged together, the laboratory is not required to perform calibration verification for each package of reagents if the packages of reagents are received in the same shipment and contain the same lot number.

The frequency of calibration is based upon the manufacturer's recommendations and calibration verification results. If calibration proves less stable than the manufacturer's recommendation, more frequent calibration may be required, as established or verified by the laboratory under 493.1213 of the regulation. Laboratories must document the frequency of calibration. See sections 493.1201-493.1285 for additional information about these requirements.

Blood-Gas Analysis Requirements

In addition to the Quality Control requirements found at 493.1245 for blood gases, the laboratory must:

- Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer.
- Test one sample of control material each eight hours of testing.
- Use a combination of calibrators and control materials that include both low and high values on each day of testing.
- Include one sample of calibration material or control material each time patients are tested unless automated instrumentation internally verifies calibration at least every 30 minutes.

Rest is not idleness, and to lie sometimes on the grass on a summer day listening to the murmur of water, or watching the clouds float across the sky, is hardly a waste of time.

--John Lubbock

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